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UNITED STATES DEPARTMENT OF COMMERCE
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Washington, D.C. 20231

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 5,156,957 was filed on November 28, 1997, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, GONAL-F, follitropin alpha/beta, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. However, the product FOLLISTIM™ (follitropin beta) was also approved on September 29, 1997 and an application for patent term extension based upon the regulatory review period of FOLLISTIM™ has been filed (U.S. Patent No. 5,270,057). If the regulatory review period for FOLLISTIM™ is the same as that of GONAL-F, then only one patent will be eligible for patent term extension.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)308-6916 (facsimile).

Karin Tyson
Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
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